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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,940	12/15/2005	Tomoyuki Uehara	PC/4-33240A	4355

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
AHMED, HASAN SYED	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
02/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,940	UEHARA ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,19,23,28,32 and 36* is/are pending in the application.

4a) Of the above claim(s) *19,23 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,28 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/14/06,3/6/07,7/7/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' IDS, filed on 14 June 2006; supplemental IDS, filed on 6 March 2007; second supplemental IDS, filed on 7 July 2009; and response to restriction requirement and election of species, filed on 9 December 2009.

* * * * *

Election/Restrictions

Applicants' election without traverse of Group IV and the formulation of claim 28 in the reply filed on 9 December 2009 is acknowledged.

Claims 19, 23, and 32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9 December 2009.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, it is unclear which ingredients listed in the claims are formulated with the tablet and which are formulated with the coating. As such, it is not possible to calculate the weight % of each ingredient to be added to the tablet or the coating. Clarification is required.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1, 5, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,605,629 ("Momose") in view of US 2003/0060488 ("Sugiyama").

Momose teaches pharmaceutical preparations comprising, *inter alia*, carboxymethycellulose calcium (see col. 20, lines 2-3). The carboxymethylcellulose calcium is disclosed to function as a disintegrant (see col. 20, line 1). It is noted that the names "carboxymethylcellulose calcium" and "carmellose calcium" are equivalent in the art (see, e.g., Sugiyama, p. [0237]). The pharmaceutical preparation may comprise a film-coating, enteric coating, or sustained-release film coating (see, e.g., col. 21, lines 5-6).

Although Momose does not disclose the combination of fluvastatin and carboxymethylcellulose calcium in a single example or embodiment, the reference explicitly teaches that the disclosed pharmaceutical preparation (i.e. comprising carboxymethylcellulose calcium) may further comprise an antihyperlipidemic agent (see col. 22, line 53). One disclosed antihyperlipidemic agent is fluvastatin (see col. 23, line 39).

Regarding claim 36, while Momose does not explicitly disclose disintegration times, the reference teaches film-coating and sustained-release film-coating (see, e.g., col. 21, lines 5-6). As in the instant application, the film coating composition may comprise hydroxypropylmethylcellulose 2910 (see preparation Example 5), Macrogol 6000 (see preparation Example 5), titanium oxide (see prepration Example 5), and yellow ferric oxide (see preparation Example 5). Particular disintegration times may be obtained by a person of ordinary skill in the art through experimentation or routine optimization.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a tablet comprising fluvastatin and carmellose calcium, as taught by Momose in view of Sugiyama. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a tablet because fluvastatin is beneficial as an antihyperlipidemic agent and carmellose calcium is beneficial as a disintegrant, as explained by Momose (see above).

*

2. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,605,629 ("Momose") in view of US 2003/0060488 ("Sugiyama"), further in view of U.S. Patent No. 7,510,728 ("Koike").

Momose and Sugiyama are discussed above.

In addition to the features noted above, the pharmaceutical preparation taught by Momose may further comprise binders such as crystalline cellulose (see col. 19, line 64) and lubricants such as talc and magnesium stearate (see col. 19, lines 59-60)

(applicable to instant claim 28). Other disclosed ingredients include precipitated calcium carbonate (see col. 21, line 9), titanium oxide (see col. 21, line 37), hydroxypropylmethylcellulose 2910 (see preparation Example 5), Macrogol 6000 (see preparation Example 5), and yellow ferric oxide (see preparation Example 5) (applicable instant to claim 28).

Momose differs from the instant application in that it does not teach sodium hydrogen carbonate as an ingredient in the pharmaceutical preparation, as recited in instant claim 28. Koike teaches a coated solid pharmaceutical preparation (see col. 11, lines 9-11). The preparation may comprise a medicinal component comprising a combination of antacids and an antihyperlipidemic agent (see col. 12, lines 16, 21, and 26). The antacid may be sodium hydrogen carbonate (see col. 13, line 12) and the antihyperlipidemic agent may be fluvastatin (see col. 14, line 8). The disclosed composition may further comprise a disintegrant such as calcium carboxymethylcellulose (i.e. carmellose calcium) (see col. 8, line 19). The particular concentrations of the various ingredients may be obtained by a person of ordinary skill in the art through experimentation or routine optimization.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a tablet comprising fluvastatin, precipitated calcium carbonate, sodium hydrogen carbonate, crystalline cellulose, carmellose calcium, talc, magnesium stearate, hydroxypropylmethylcellulose 2910, macrogol 6000, titanium oxide, and yellow ferric oxide, as taught by Momose in view of Sugiyama, further in view of Koike. One of ordinary skill in the art at the time the invention was made would have

been motivated to make such a tablet because fluvastatin is beneficial as an antihyperlipidemic agent, carmellose calcium is beneficial as a disintegrant, and sodium hydrogen carbonate is beneficial as an antacid as explained by Momose and Koike (see above).

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615